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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/288,326	04/08/99	SACHS	G 17282

HM12/0215

ALLERGAN INC
2525 DUPONT DRIVE
IRVINE CA 92612

EXAMINER	
CLEMENS,K	
ART UNIT	**PAPER NUMBER**
1644	5

DATE MAILED: 02/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/288,326	Applicant(s) Sachs et al.
	Examiner Karen Clemens	Group Art Unit 1644

☒ Responsive to communication(s) filed on 9/3/99.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-40 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-40 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. For examination purposes, it appears that claims 9-12 should be dependent on claim 5 and not on 8-11, respectively. Applicant is invited to clarify and amend the claims accordingly.

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, drawn to a composition comprising a binding element, a translocation element and a therapeutic element classified in Class 514, subclass 12 and Class 424, subclass 94.1.

II. Claims 25-40, drawn to a method of treatment for acute pancreatitis, classified in class 514, subclass 12, and Class 424, subclass 94.1.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be practiced with materially different processes such as pancreatic cell identification or imaging.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is further required under 35 U.S.C. 121, if Group I is elected, to elect a composition comprising:

1. A specific binding element:
    a) SEQ ID No. 2
    b) SEQ ID No. 3
    c) SEQ ID No. 4
    d) SEQ ID No. 5
    e) SEQ ID No. 6

2. A specific translocation element (such as the ones disclosed in the specification, page 21, lines 7-22, for example)
    a) N-terminal peptide half of the heavy chain of a *Clostridium tetanus* neurotoxin
    b) N-terminal peptide half of the heavy chain of a *Clostridium botulinum* neurotoxin

3. A specific therapeutic element cleaving the SNARE protein (such as the ones disclosed in the specification, page 9, lines 8-20, for example):
    a) BoNT/B, D, F, G or TeNT cleaving VAMP
    b) BoNT/C1 cleaving Syntaxin
    c) BoNT/A or E cleaving SNAP-25

4. A specific spacer moiety:
    a) a hydrocarbon
    b) a polypeptide other than an immunoglobulin hinge region
    c) a proline-containing polypeptide identical or analogous to an immunoglobulin hinge region such as SEQ ID NO:11

8. Applicant is further required under 35 U.S.C. 121, if Group II is elected, to elect a method for administering a specific composition comprising:

1. A specific translocation element (such as the ones disclosed in the specification, page 21, lines 7-22, for example)
    a) N-terminal peptide half of the heavy chain of a *Clostridium tetanus* neurotoxin
    b) N-terminal peptide half of the heavy chain of a *Clostridium botulinum* neurotoxin

2. A specific therapeutic element cleaving the SNARE protein(such as the ones disclosed in the specification, page 9, lines 8-20, for example):
    a) BoNT/B, D, F, G or TeNT cleaving VAMP
    b) BoNT/C1 cleaving Syntaxin
    c) BoNT/A or E cleaving SNAP-25

3. A specific spacer moiety:
    a) a hydrocarbon
    b) a polypeptide other than an immunoglobulin hinge region

c) a proline-containing polypeptide identical or analogous to an immunoglobulin hinge region.

9. The various binding elements such as SEQ ID NO:2, 3, 4, 5, 6 have different amino acid sequences and are patentably distinct. They are independent in operation and one does not require the other for its ultimate use. They are patentable over one another.

The translocation elements such as the one from the N-terminal peptide half of the heavy chain of *Clostridium tetanus* neurotoxin or from the N-terminal peptide half of the heavy chain of *Clostridium botulinum* neurotoxin have different amino acid sequences and are patentably distinct. They are independent in operation and one does not require the other for its ultimate use. They are patentable over one another.

The therapeutic elements target different SNARE proteins such as Syntaxin, SNAP-25 and VAMP and are patentably distinct. They are independent in operation and one does not require the other for its ultimate use. They are patentable over one another.

The spacer moiety such as a hydrocarbon, a polypeptide other than an immunoglobulin hinge region, a proline-containing polypeptide identical or analogous to an immunoglobulin hinge region (SEQ ID NO:11) have different compositions or amino acid sequences and are patentably distinct. They are independent in operation and one does not require the other for its ultimate use. They are patentable over one another.

10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 25 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Due to the complexity of the claimed invention an oral restriction was not made.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Clemens whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Karen Clemens, Ph.D.
Patent Examiner
Technology Center 1600
February 11, 2000

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800/1640